

REMARKS

Reconsideration of this application is respectfully requested. Claim 1 has been amended to call for a method of surveillance for the presence of a chemical, biological, or radiological agent wherein street debris materials are collected from a street sweeper on a route through a city street and debris is collected from a city street. Support for this amendment is found throughout the specification, for example, at page 7, lines 5 and 6; and page 24, lines 3-5.

No new matter has been added. Upon entry of this amendment, claims 1, 3-9, 11-15, 20, 22-24, 26-29 and 32-46 are pending and under consideration.

Rejections under 35 U.S.C. § 102(a)

Claims 1, 3, 5-9, 11-15, 22-24, 26-27, and 37-43 stand rejected as anticipated by Hoffmaster, et al., *Emerging Inf. Diseases*, 8(10):1-12 (2002) (“Hoffmaster”). The Examiner contends that Hoffmaster discloses each element of these claims (see Office Action, pages 3-5).

Applicants submit that in order for a reference to anticipate a claim, the reference must disclose each and every limitation of the claimed invention. *Dana Corp. v. Am. Axle & Mfg., Inc.*, 61 USPQ 2d 1609 (Fed. Cir. 2002). The present claims call for a method of surveillance for the presence of a chemical, biological, or radiological agent that includes at least assaying a sample derived from street debris materials (collected from a sample domain for the presence of a chemical, biological, or radiological agent). Claim 1 calls for a method wherein the sample domain is a route undertaken by a street sweeper machine and comprises at least one collection point from which the materials are collected from a city street.

Hoffmaster does not disclose a method of surveillance for the presence of a chemical, biological, or radiological agent by sampling debris obtained from “at least one sample from a collection of street debris” or from “a route undertaken by a street sweeper machine through a city street and comprises at least one collection point from which the materials are collected from a city street” as called for in the pending claims.

Applicants also note that there is no teaching or suggestion in Hoffmaster that a method of surveillance for harmful agents in materials that are collected from a city street would be successful.

Rejections under 35 U.S.C. § 103

Claim 29 has been rejected as obvious over Schlimme, et al., *App. Environ. Micro.*, pages 2754-2757 (1999) (“Schlimme”). According to the Examiner, Schlimme teaches detecting the presence of multiple different bacterial strains including two *Bacillus* strains (*B. cereus* and *B. thuringiensis*) by adding bacteria to *Tetrahymena pyriformis*. The Examiner concedes that Schlimme does not disclose the analysis of *B. anthracis*, but that it would have been obvious to do so.

This rejection is respectfully traversed.

For a claim to be obvious under U.S. patent law, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Additionally, the Patent Office must articulate the reason(s) why a skilled artisan “would have recognized” that combining the prior art “would have yielded nothing more than predictable results” (see Examination Guidelines, Department of Commerce, *Federal Register*, 72(195):57529 (October 10, 2007). Additionally, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983). Applicants submit that for the reasons discussed below, a person of ordinary skill in the art would not have predicted the success of the claimed invention in view of the cited art, and that Schlimme actually teaches away from the rejected claims.

Schlimme discloses a bioassay that employs protozoa to assess the relative toxicity of certain bacteria (see Schlimme, abstract). The toxicity bioassay involves detecting toxicant-producing bacteria that can present a potential biohazard by feeding potentially harmful bacteria to *T. pyriformis* (the protozoa), and observing the protozoa for any subsequent death. The

resulting protozoan death rate is used to assess the potential toxicity of the bacteria (see Schlimme, page 2754, third paragraph). The bioassay is designed to identify bacterial strains that synthesize toxic secondary metabolites. The Examiner contends that the bioassay disclosed in Schlimme was used to detect two strains of *Bacillus* (*cereus* and *thuringiensis*).

B. anthracis releases a secondary metabolite called tripartite toxin (composed of lethal factor, edema factor and protective antigen) which is known to be the primary agent of tissue destruction, bleeding, and death. In order for Schlimme to render the present claims obvious, a skilled artisan would have had to recognize that the bioassay disclosed in Schlimme would predictably demonstrate that *T. pyriformis* protozoa are susceptible to the toxic agent released by *B. anthracis*, i.e., tripartite toxin. The Examiner has not provided any evidence that such susceptibility exists or was well known in the art at the time the application was filed. Therefore, Applicants submit that despite any potential similarity of the *B. anthracis* to the two *Bacillus* strains disclosed in Schlimme, a person of ordinary skill in the art would not have had a reasonable expectation of success using the Schlimme test to detect *B. anthracis* because its secondary toxin would not *necessarily* behave the same as toxins released by *B. cereus* or *B. thuringiensis*. Also, since different strains of bacteria also have different characteristics, a skilled artisan would not have been motivated to attempt the Schlimme bioassay using *B. anthracis* without knowledge that the protozoa are susceptible to tripartite toxin.

Furthermore, contrary to the Examiner's position, Schlimme *actually* discloses that neither of the *Bacillus* strains evaluated using the Schlimme bioassay caused protozoan death (see Schlimme, page 2757, third paragraph). In other words, the bioassay relied upon by Schlimme to indicate bacterial toxicity did not demonstrate positive results for either of the two *Bacillus* strains tested. Schlimme states: "The strains of the highly specific insect pathogen *Bacillus thuringiensis* were innocuous for *Tetrahymena*, and so were the food-poisoning *Bacillus cereus* strains." *Id.* Based on these results, a skilled artisan would not have predicted the success of the claimed invention because the Schlimme bioassay did not detect either of the *Bacillus* bacterial strains tested (see data presented in Table 3). In this regard, Schlimme actually teaches away from the claimed invention because the Schlimme bioassay was wholly ineffective for detecting *Bacillus* toxicity.

Since a skilled artisan would not have predicted the success of the claimed invention in view of Schlimme, and since the Schlimme bioassay actually teaches away from the claimed method, the present claims are not obvious. Accordingly, the rejection for obviousness should be withdrawn.

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Claims 32-34 have been rejected as obvious over the teachings of Schlimme in view of Weinbauer, *App. Environ. Micro.*, p. 3776-3783 (1998) (“Weinbauer”), and further in view of Agarwal, et al., *Current Sciences*, 83:697-699 (2002) (“Agarwal”). The Examiner contends that Weinbauer discloses filtration of bacterial communities through screen filters to isolate the desired bacteria, and Agarwal discloses culturing *B. anthracis* followed by heating at 60°C to inactivate vegetative cells (*see* Office action, page 8).

This rejection is respectfully traversed.

Weinbauer discloses a method of using monoclonal antibodies to determine the depth distributions of two populations of two bacterial populations in a lake. In the Weinbauer method, large quantities of bacteria are filtered to separate various components, such as bacteria, phytoplankton, and virus etc. Filtration is carried using a variety of filtration steps and membrane sizes. Agarwal discloses methods of isolating and identification of *B. anthracis* by detecting *Bacillus* spores in soil samples using an immunofluorescence assay (*see* Agarwal, page 697, col. 1). As part of this method, Agarwal discloses heat-inactivating spores by heating them to 60°C for 90 minutes (*id.* at col. 2).

Applicants respectfully submit that although Weinbauer and Agarwal disclose certain features of claims 32-34 (membrane filtration and heat inactivation of vegetative bacteria), claims 32-34 depend directly or indirectly from base claim 29. As discussed above, claim 29 is not obvious over the cited art because a person of ordinary skill in the art would not have predicted the success of the claimed invention in view of Schlimme due to bacterial strain differences (i.e., there is no suggestion that the bioassay disclosed in Schlimme would have been

successful with *B. anthracis*), and because Schlimme actually *teaches away* from using the bioassay disclosed therein for detecting *Bacillus* at all.

Weinbauer and Agarwal do not cure the deficiencies of the Schlimme bioassay, and therefore, claims 32-34 are not obvious over the cited references, either alone or in combination. Accordingly, this rejection should be withdrawn.

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Claim 34 has been rejected as obvious over Schlimme in view of Weinbauer. The Examiner states that it would have been obvious to improve the methods of assessing overall bacterial toxicity as taught by Schlimme to include a filtration step to obtain the desired bacteria, as disclosed in Weinbauer (*see* Office Action, page 9).

This rejection is respectfully traversed.

Weinbauer discloses various membrane filtration steps. Rejected claims 34 depends from claim 29. However, for the reasons discussed above, claim 29 is not obvious over Schlimme because the bioassay disclosed in Schlimme would not have been predictive for detecting *B. anthracis*, as recited in the present claims, and in fact teaches away from using such a bioassay to detect *Bacillus* strains. Weinbauer does not cure the deficiencies of Schlimme because Weinbauer also fails to teach or suggest a bioassay for detecting *Bacillus*, and therefore, claim 34 is also not obvious over Weinbauer and Schlimme. Accordingly, Applicants respectfully request that this rejection be withdrawn.

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Finally, claims 35 and 36 have been rejected as obvious over Schlimme in view of Weinbauer and Agarwal. In view of these references, the Examiner concludes that it would have been obvious to heat inactivate cells prior to filtration depending on their size (*see* Office Action, pages 10-11).

This rejection is also respectfully traversed.

Claims 35 and 36 also depend from base claim 29. For the reasons discussed above, claim 29 is not obvious over Schlimme because the bioassay disclosed in Schlimme would not have been predictive for detecting *B. anthracis*, as recited in the present claims, and in fact teaches away from using such a bioassay to detect *Bacillus* strains. Weinbauer and Agarwal do not cure this deficiency, and therefore, claims 35 and 36 are also not obvious over the cited references. Accordingly, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By 
Amy G. Klaman, Ph.D.

Registration No.: 48,155
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicants